DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 3, 2014

Carl Zeiss Meditec AG
Ms. Mandy Ambrecht
Staff Regulatory Affairs Specialist
5160 Hacienda Drive
Dublin, CA 94568

Re: K141297
Trade/Device Name: FORUM® Glaucoma Workplace
Regulation Number: 21 CFR 892-2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: II
Product Code: NFJ
Dated: August 29, 2014
Received: September 2, 2014

Dear Ms. Ambrecht:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141297

Device Name
FORUM® Glaucoma Workplace

Indications for Use *(Describe)*
FORUM Glaucoma Workplace is a FORUM software application intended for the management, display, and analysis of visual field and optical coherence tomography data. The FORUM Glaucoma Workplace is indicated as an aid to the detection, measurement, and management of visual field defects and progression of visual field loss.

FORUM Glaucoma Workplace is also intended for generating reports that contain results from perimetry, optical coherence tomography and fundus photography.

FORUM Glaucoma Workplace implements Cirrus algorithms and normative databases for retinal nerve fiber layer thickness, ganglion cell plus inner plexiform thickness and optic nerve head measurement and Humphrey Field Analyzer algorithms and databases for visual field measurements and Guided Progression Analysis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SECTION 5. 510(K) SUMMARY

5. 510(k) Summary

510(k) SUMMARY
(per 21 CFR §807.92)

FORUM Glaucoma Workplace

GENERAL INFORMATION

Manufacturer:	Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 D-07745 Jena, Germany +49 3641220-667 (phone) +49 3641220-282 (fax) Establishment Registration Number: 9615030
Contact Person:	Mandy Ambrecht Staff Regulatory Affairs Specialist Carl Zeiss Meditec, Inc. 5160 Hacienda Drive Dublin, CA 94568 (925) 557-4561 Phone (925) 557-4259 Fax E-mail: mandy.ambrecht@zeiss.com
Date prepared:	September 15, 2014
Device	System, Image Management, Ophthalmic
Classification:	21 CFR 892.2050
Device Class:	II
Product Code:	NFJ
Common Name:	Picture Archiving and Communications System
Trade/Proprietary Name:	FORUM Glaucoma Workplace

SECTION 5. 510(K) SUMMARY

PREDICATE DEVICES:

Company:	Carl Zeiss Meditec AG
Device:	FORUM Glaucoma Workplace (K130648)
Company:	Carl Zeiss Meditec AG
Device:	FORUM (K122938)
Company:	Carl Zeiss Meditec, Inc.
Device:	Cirrus HD-OCT with Retinal Nerve Fiber Layer (RNFL), Macular, Optic Nerve Head and Ganglion Cell Normative Databases (K111157)
Company:	Carl Zeiss Meditec AG
Device	CIRRUS photo (K112184)

INDICATIONS FOR USE

FORUM Glaucoma Workplace is a FORUM software application intended for the management, display, and analysis of visual field and optical coherence tomography data. The FORUM Glaucoma Workplace is indicated as an aid to the detection, measurement, and management of visual field defects and progression of visual field loss.

FORUM Glaucoma Workplace is also intended for generating reports that contain results from perimetry, optical coherence tomography and fundus photography.

FORUM Glaucoma Workplace implements Cirrus algorithms and normative databases for retinal nerve fiber layer thickness, ganglion cell plus inner plexiform thickness and optic nerve head measurement and Humphrey Field Analyzer algorithms and databases for visual field measurements and Guided Progression Analysis.

DEVICE DESCRIPTION

FORUM Glaucoma Workplace is a FORUM software application intended for the management, display, and analysis of visual field and optical coherence tomography data.

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FORUM Glaucoma Workplace implements Cirrus algorithms and normative databases for retinal nerve fiber layer thickness, ganglion cell plus inner plexiform thickness and optic nerve head measurement and Humphrey Field Analyzer algorithms and databases for visual field measurements and Guided Progression Analysis.

FORUM Glaucoma Workplace provides a means to review and analyze data from various visual field examinations to identify progressive visual field loss. FORUM Glaucoma Workplace utilizes Humphrey® Field Analyzer (HFA) algorithms and databases including STATPAC and Guided Progression Analysis (GPA) to process visual field data and generate visual field reports. GPA compares visual field test results of follow-up tests to an established baseline over time and determines if there is change that exceeds the expected test-retest variability.

FORUM Glaucoma Workplace generates combined reports that contain results from perimetry, optical coherence tomography and fundus photography. FORUM Glaucoma Workplace implements Cirrus algorithms and databases for retinal nerve fiber layer (RNFL) thickness, ganglion cell plus inner plexiform layer thickness and optic nerve head (ONH) measurements included in these reports.

The created reports and the Guided Progression Analysis provide a comprehensive overview of the structural and functional exam results to aid health care professionals in the measurement, and management of visual field defects and progression of visual field loss.

The following are the main functionalities of FORUM Glaucoma Workplace:

- Data retrieval and report storage
- Managing, analyzing and displaying visual field exams and OCT exams
- Creation of visual field reports and combined reports

FORUM Glaucoma Workplace retrieves HFA visual field test data from the FORUM Archive, uses the HFA algorithms and databases to process the visual field raw data, then generates and displays visual field reports.

FORUM Glaucoma Workplace creates combined reports using HFA visual field exam data (functional information) and Cirrus acquisition data (structural information); fundus images stored in FORUM may also be added to the reports. The reports generated by FORUM Glaucoma Workplace are stored as DICOM Encapsulated PDFs in the FORUM Archive. FORUM Glaucoma Workplace displays interactive screens and the generated visual field reports. These reports include those previously offered by the HFA II and HFA II –*i*: Single Field Analysis; Three in One; Numeric; Suprathreshold; Kinetic Reports; Overview; Guided Progression Analysis (GPA) Summary, Full GPA, GPA Last Three Follow-up and Single Field Analysis (SFA) GPA.

FORUM Glaucoma Workplace manages Cirrus OCT data to generate combined functional (perimetry) and structural (OCT) reports. These combined reports contain the results from perimetry, OCT and fundus photography.

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FORUM Glaucoma Workplace processes Cirrus OCT data by implementing the Cirrus algorithms and databases offered by Cirrus HD-OCT and CIRRUS photo. The databases offered by Cirrus HD-OCT are used within FORUM Glaucoma Workplace for comparison to Cirrus HD-OCT data; the databases offered by CIRRUS photo are used within FORUM Glaucoma Workplace for comparison to CIRRUS photo data.

FORUM Glaucoma Workplace provides two types of combined reports:

1. 24-2/30-2 and RNFL (for Cirrus HD-OCT and CIRRUS photo data):
   This report presents the visual field test result comprised of either the 24-2 or 30-2 test pattern combined with a Retinal Nerve Fiber Layer (RNFL) report.

2. 10-2 and GCA (only for Cirrus HD-OCT data):
   This report presents a visual field test result comprised of the central 10-2 test pattern combined with a Ganglion Cell Analysis (GCA) report.

Elements from the visual field reports that are provided in the Combined Reports include the Graytone plot, Pattern Deviation and Total Deviation plots (using probability symbols) and a key to the probability symbols. In addition, the Reliability Indices (Fixation Losses; False Positive errors; False Negative errors) and Global Indices [Visual Field Index (VFI); Mean Deviation (MD); Pattern Standard Deviation (PSD) and Glaucoma Hemifield Test (GHT)] are provided.

Elements from the Cirrus OCT reports that are provided in the Combined Report include the Retinal Nerve Fiber Layer Thickness (RNFL) Deviation Map, Average RNFL Thickness and Optic Nerve Head Summary. FORUM Glaucoma Workplace also provides the Ganglion Cell Analysis (GCA) Thickness Deviation Map and GCA parameters table for Cirrus HD-OCT data.

After launching FORUM Glaucoma Workplace from the FORUM application, the user can select from four tabs: Visual Fields; Overview; GPA and Create Reports. Within these tabs, FORUM Glaucoma Workplace provides tools for the management, display and analysis of visual field exam data and the creation of reports.

Visual Fields Tab

FORUM Glaucoma Workplace displays a range of visual field tests (Threshold, Suprathreshold and Kinetic) that have been stored in FORUM. The exam list includes the exam date, test pattern, test strategy, and the stimulus color, size, and background for each selected patient. From the Visual Field tab, users can create reports for later retrieval in FORUM Viewer and/or be printed.

Overview Tab

FORUM Glaucoma Workplace creates and displays visual field reports for visual field tests provided the visual field examination results have been stored in FORUM. These reports include the Overview and Single Field Analysis. The Overview report contains the data of all existing tests selected. The Single Field Analysis report contains data from a single central threshold test.

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GPA Tab

FORUM Glaucoma Workplace contains the same GPA algorithms and databases as offered in the Humphrey® Field Analyzer II and II-*i* and allows GPA to be performed on a computer running FORUM independent of and apart from the visual field instrument itself. Within the GPA tab, GPA information is provided on interactive screens.

GPA analysis can be performed for any patient who has at least two baseline visual field tests. These tests must have been performed with the Full Threshold, Swedish Interactive Threshold Algorithm (SITA) Standard, or SITA Fast test strategies. Also, at least one follow-up visual field test must have been performed using either the SITA Standard or SITA Fast test strategy. With FORUM Glaucoma Workplace, the user can set an optional, second baseline.

From the GPA tab, users can create four types of GPA reports: Full GPA, GPA Summary, GPA Last Three Follow-up and Single Field Analysis (SFA) GPA. A Single Field Analysis report can also be created within the GPA tab.

FORUM Glaucoma Workplace allows the user to interact with the available data. When viewing the GPA on the screen, the user can hold the mouse pointer over a particular area and a small tooltip will appear with details regarding the particular test. In addition, the user can add notes about an exam through the Comments feature and view previous comments about any exam.

Create Reports Tab

FORUM Glaucoma Workplace provides the user with the option of creating different report types, such as Single Field Analysis, Kinetic, or Suprathreshold using exam data stored in FORUM. Several reports of the same type can also be generated in one simple procedure, for example, if the user wants to create or print Single Field Analysis reports for every Threshold exam for a particular patient.

Technological Characteristics

FORUM Glaucoma Workplace is connected to FORUM via an internal interface; it consists of a server and client that integrate into an existing FORUM Archive and Viewer installation. Once FORUM Glaucoma Workplace is installed and licensed, the new functionality becomes available in FORUM Viewer.

The FORUM Glaucoma Workplace server is installed on the FORUM server. The data access components are located on the server. The server installation enables FORUM Glaucoma Workplace to retrieve HFA and OCT exam data stored in the FORUM Archive. It also contains the algorithms and databases for data management and creation of visual field reports and reports that contain results from perimetry, optical coherence tomography, and fundus photography (Combined Reports).

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The client is installed on the FORUM Viewer. The display components are located on the client. The client installation enables FORUM Glaucoma Workplace to display visual field results, optical coherence tomography data and the user interaction information.

The reports are displayed on a computer monitor with interactive screens using the FORUM Viewer. The created reports may be stored as DICOM Encapsulated PDFs in the FORUM Archive.

SUBSTANTIAL EQUIVALENCE

The FORUM Glaucoma Workplace is substantially equivalent to the predicate devices with regard to the indications for use statement and is functionally equivalent to the predicate devices.

FORUM Glaucoma Workplace and the predicate device, FORUM (K122938), present reports which contain perimetry results and optical coherence tomography data. Both devices create combined reports containing structure and function data from perimetry and optical coherence tomography. The exam data received from the acquisition devices are presented in one report. FORUM (K122938) archives and displays fundus images. FORUM Glaucoma Workplace creates combined reports that can include fundus images, whereas the combined reports created in FORUM does not. Transferring and accepting data are also enabled by both devices. Both devices utilize client-server systems.

FORUM Glaucoma Workplace and the predicate device, FORUM Glaucoma Workplace (K130648) are software devices. Both devices retrieve visual field data from the FORUM Archive, manage and display visual field exam data and create visual field reports. Both devices provide STATPAC and Guided Progression Analysis and their associated data plots.

FORUM Glaucoma Workplace and the predicate device, FORUM Glaucoma Workplace (K130648) both provide visual field analysis functionalities and use Guided Progression Analysis to evaluate a patient's test results over time to determine if there has been any change that exceeds the expected test-retest variability since the baseline was established. If such change is determined, both devices inform the reviewer with a "GPA Alert". Both devices use data to create the GPA analysis and manage data in that the GPA analysis can be updated with regards to establishing new baselines and/or utilizing new exams for follow-up which in turn is utilized in the management of progression of visual field loss.

Both devices allow the user to interactively change the visual field tests included as a Baseline or Follow-up test when performing GPA and to see the result of the change immediately on the computer monitor. The visual field reports (GPA, Single Field Analysis, Overview) can be viewed on a computer monitor or in a printed format. The selected earliest Baseline test is indicated in red color if it shows a significant learning effect in the VFI Plot.

While both devices retrieve visual field data from the FORUM Archive, a primary difference with the proposed device is that OCT data can also be retrieved from the FORUM Archive, whereas this option was not available with the predicate.

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Other notable differences with the proposed device which were not available with the predicate device include additional enhancements for the user such as the option to set a second baseline; the ability to enter and view comments for each exam plotted in the GPA plot; showing the MD and IOP Plot over time and synchronized scrolling between OD and OS in the Overview screen. FORUM Glaucoma Workplace and the predicate device Cirrus HD-OCT with Retinal Nerve Fiber Layer (RNFL), Macular, Optic Nerve Head and Ganglion Cell Normative Databases (K111157) provide the same functionality for the management of optical coherence tomography (OCT) exam results from Cirrus HD-OCT. The exam results are displayed in relation to normative data.

FORUM Glaucoma Workplace and the predicate device, Cirrus HD-OCT with Retinal Nerve Fiber Layer (RNFL), Macular, Optic Nerve Head and Ganglion Cell Normative Databases (K111157), use the same algorithms and databases for the Cirrus Retinal Nerve Fiber Layer (RNFL), Optic Nerve Head (ONH), and Ganglion Cell plus inner plexiform layer (GCA) thickness information on the combined reports for Cirrus HD-OCT exams.

FORUM Glaucoma Workplace and the predicate, CIRRUS photo (K112184), provide the same functionality for management of optical coherence tomography (OCT) exam results from CIRRUS photo. The exam results are displayed in relation to normative data.

FORUM Glaucoma Workplace and the predicate device, CIRRUS photo (K112184) use the same algorithms and databases for the Cirrus Retinal Nerve Fiber Layer (RNFL) and Optic Nerve Head information on the combined reports for CIRRUS photo exams.

A difference between the proposed device and the predicate devices, Cirrus HD-OCT with Retinal Nerve Fiber Layer (RNFL), Macular, Optic Nerve Head and Ganglion Cell Normative Databases (K111157) and CIRRUS photo (K112184), is that the predicate devices are comprised of hardware and software whereas the proposed device is comprised only of software. In addition, both of the Cirrus OCT devices were designed to image and measure anterior and posterior ocular structures as well as analyze the resulting data, whereas the proposed device is used to analyze Cirrus OCT data but is not used to acquire images.

PERFORMANCE DATA

Performance testing was conducted on FORUM Glaucoma Workplace and it was found to perform as intended. Each function and/or feature was tested by means of an appropriate test case or test specification. The verification testing demonstrates that the device performance complies with specifications and requirements identified for FORUM Glaucoma Workplace.

Verification and validation was conducted to ensure that the medical device meets the product and user requirements and to support a determination of substantial equivalence to the predicate devices.

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The software verification activities were divided into three phases:

- Tests accompanying development (including code inspections)
- Module and integration test phase – stabilization phase
- System verification

As part of the verification testing, the visual field reports generated on the HFA II-*i* and OCT test reports generated on the Cirrus HD-OCT and CIRRUS photo were compared to the reports generated by FORUM Glaucoma Workplace using the same test data to verify that the results contained in both reports were equivalent.

The client and server operating systems were also evaluated during verification. The results determined that FORUM Glaucoma Workplace is suitable for the same operating systems for which the respective FORUM Archive & Viewer version is released and that it is suitable under the following operating systems:

Operating Systems (server):

- Microsoft Windows 7 (64 bit) with Service Pack 1
- Microsoft Windows 8 (64 bit)
- Microsoft Windows Server 2008 R2 with Service Pack 1

Operating Systems (client):

- Windows XP (32 bit) with Service Pack 3
- Windows 7 (32 or 64 bit) with Service Pack 1
- Windows 8 (64 Bit)
- Windows Server 2008 R2 with Service Pack 1
- Windows Server 2008 (TS) R2 (64 bit) with Service Pack 1
- OS X 10.8 (Mountain Lion)

Validation of clinical functionalities was completed by ophthalmologists in three countries using FORUM Glaucoma Workplace software as well as representative data (sample data that is representative of true clinical cases) installed on a computer and used as a parallel system. The validation participants used the system, executed test cases that simulated the use of the device in a clinical environment and completed questionnaires rating the various aspects of the software.

Verification and validation activities were successfully completed and prove that the product FORUM Glaucoma Workplace meets its requirements and performs as intended.

SUMMARY

As described in this 510(k) Summary, all testing deemed necessary was conducted on FORUM Glaucoma Workplace to ensure that the device is as safe and effective as the predicate devices.